

### AMENDMENTS TO THE CLAIMS

In accordance with Rule 1.121, a complete claim listing is presented below, including appropriate status identifiers. Changes in the amended claims are shown by strikethrough for deleted material, and by underlining for added material.

1. (Currently Amended) A composition for sustained release, comprising:  
a carrier material comprising a non-polymeric, non-water soluble liquid material having a viscosity of at least 5,000 cP at 37 °C that does not crystallize neat under ambient physiological conditions;  
growth hormone; and  
a multivalent metal cation;  
wherein the composition releases at most 4% of the growth hormone *in vitro* within the first 24 hours as determined by Release Rate Determination.
2. (Original) The composition of claim 1, wherein the liquid material is a stearate ester, a stearate amide, a long-chain fatty acid amide, a long-chain fatty alcohol, a long-chain ester, or a disaccharide ester.
3. (Original) The composition of claim 1, wherein the liquid material is acetylated sucrose distearate.
4. (Original) The composition of claim 1, wherein the liquid material is disaccharide acetate butyrate.
5. (Original) The composition of claim 4, wherein the liquid material is sucrose acetate isobutyrate.
6. (Original) The composition of claim 5, wherein the growth hormone is human growth hormone.
7. (Original) The composition of claim 5, wherein the multivalent metal cation has a valence of two.

8. (Original) The composition of claim 7, wherein the multivalent metal cation is  $\text{Zn}^{2+}$ .
9. (Original) The composition of claim 5, further comprising a solvent.
10. (Currently Amended) A composition for sustained release, comprising:  
sucrose acetate isobutyrate;  
a solvent;  
zinc; and  
growth hormone;  
wherein the composition releases at most 4% of the growth hormone *in vitro*  
within the first 24 hours as determined by Release Rate Determination.
11. (Original) The composition of claim 10, wherein the composition has a viscosity less than 1000 cP at room temperature.
12. (Original) The composition of claim 10, wherein the composition has a viscosity less than 200 cP at room temperature.
13. (Original) The composition of claim 10, wherein the solvent is ethanol, benzyl benzoate, miglyol, propylene carbonate, benzyl alcohol, ethyl lactate, glycofurol, N-methylpyrrolidone, 2-pyrrolidone, propylene glycol, acetone, methyl acetate, ethyl acetate, methyl ethyl ketone, triacetin, dimethylformamide, dimethylsulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, or 1-dodecylazacycloheptan-2-one.
14. (Original) The composition of claim 10, wherein the solvent is ethanol, benzyl benzoate, miglyol, propylene carbonate, or benzyl alcohol.
15. (Original) The composition of claim 10, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 85:15 w/w.

16. (Original) The composition of claim 10, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 75:25 w/w.
17. (Original) The composition of claim 10, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 70:30 w/w.
18. (Original) The composition of claim 10, wherein the molar ratio of zinc to growth hormone is from 100:1 to 1:1.
19. (Original) The composition of claim 10, wherein the molar ratio of zinc to growth hormone is from 20:1 to 1:1.
20. (Original) The composition of claim 10, wherein the molar ratio of zinc to growth hormone is from 10:1 to 1:1.
21. (Original) The composition of claim 10, comprising:
  - a sucrose acetate isobutyrate to solvent ratio from 50:50 w/w to 85:15 w/w, wherein the sucrose acetate isobutyrate and solvent together form a liquid; and
  - a zinc to growth hormone molar ratio from 100:1 to 1:1, wherein the zinc and growth hormone together form a complex.
22. (Original) The composition of claim 21, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 75:25 w/w.
23. (Original) The composition of claim 21, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 70:30 w/w.
24. (Original) The composition of claim 21, wherein the molar ratio of zinc to growth hormone is from 20:1 to 1:1.
25. (Original) The composition of claim 21, wherein the molar ratio of zinc to growth hormone is from 10:1 to 1:1.

26. (Original) A method of administering growth hormone, comprising:  
injecting the composition of claim 1 into a patient in need of said growth hormone.
27. (Cancelled)
28. (Original) The method of claim 26, wherein less than 0.2% of the growth hormone is released within 24 hours of administration.
29. (Original) The method of claim 26, wherein the percentage of the growth hormone released within a 24 hour period is from 0.05% to 3%.
30. (Original) The method of claim 26, wherein the percentage of the growth hormone released within a 24 hour period is from 1% to 3%.
31. (Original) A method of administering growth hormone, comprising:  
injecting the composition of claim 10 into a patient in need of said growth hormone.
32. (Cancelled)
33. (Original) The method of claim 31, wherein less than 0.2% of the growth hormone is released within 24 hours of administration.
34. (Original) The method of claim 31, wherein the percentage of the growth hormone released within a 24 hour period is from 0.05% to 3%.
35. (Original) The method of claim 31, wherein the percentage of the growth hormone released within a 24 hour period is from 1% to 3%.
36. (Original) A method of administering growth hormone, comprising:  
injecting the composition of claim 21 into a patient in need of said growth hormone.
37. (Cancelled)

38. (Original) The method of claim 36, wherein less than 0.2% of the growth hormone is released within 24 hours of administration.
39. (Original) The method of claim 36, wherein the percentage of the growth hormone released within a 24 hour period is from 0.05% to 3%.
40. (Original) The method of claim 36, wherein the percentage of the growth hormone released within a 24 hour period is from 1% to 3%.
41. (Currently Amended) A method of making a sustained release composition, comprising:
- mixing a complex and a liquid carrier to form said sustained release composition;
  - wherein said liquid carrier comprises sucrose acetate isobutyrate; and
  - wherein said complex comprises growth hormone and  $Zn^{2+}$ ;
  - wherein said sustained release composition releases at most 4% of the growth hormone *in vitro* within the first 24 hours as determined by Release Rate Determination.
42. (Original) The method of claim 41, wherein said sustained release composition has a viscosity less than 1000 cP at room temperature.
43. (Original) The method of claim 41, wherein said sustained release composition has a viscosity less than 200 cP at room temperature.
44. (Original) The method of claim 41, wherein the molar ratio of zinc to growth hormone is from 100:1 to 1:1.
45. (Original) The method of claim 41, wherein the molar ratio of zinc to growth hormone is from 10:1 to 1:1.
46. (Original) The method of claim 41, wherein said liquid carrier further comprises a solvent.

47. (Original) The method of claim 46, wherein said solvent is ethanol, benzyl benzoate, miglyol, propylene carbonate, or benzyl alcohol.
48. (Original) The method of claim 46, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 85:15 w/w.
49. (Original) The method of claim 46, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 70:30 w/w.
50. (Currently Amended) The method of claim 46, wherein said sustained release composition comprises:
- a sucrose acetate isobutyrate to solvent ratio from 50:50 w/w to 85:15 w/w, wherein the sucrose acetate isobutyrate and solvent together form said liquid carrier;
  - a zinc to growth hormone molar ratio from 100:1 to 1:1, wherein the zinc and growth hormone together form said complex; and
  - a liquid carrier to complex ratio from 95:5 ~~w/w~~ v/w to 85:15 ~~w/w~~ v/w.
51. (Original) The method of claim 50, wherein the ratio of sucrose acetate isobutyrate to solvent is from 50:50 w/w to 70:30 w/w.
52. (Original) The method of claim 50, wherein the molar ratio of zinc to growth hormone is from 10:1 to 1:1.